MINUTES

HUMAN SUBJECTS RESEARCH ADVISORY COMMITTEE
Friday, September 8, 2006
CRC Medical Board Room
3:00 p.m.

Present

Dr. Michael Gottesman, Chair
Dr. Fabio Candotti, NHGRI
Dr. Michael Collins, NIDCR, for Dr. Mitchell Max
Dr. Edmond Fitzgibbon, NEI
Dr. David Goldman, NIAAA
Dr. Denise Gonzales, FELCOM/CC
Ms. Christine Grady, CRC/DCB
Dr. Rohan Hazra, NCI
Dr. Barbara Karp, NINDS/NIDCD/NIA
Dr. Sarah Kindrick, for Ms.LisaCoronado, ORS/DRS.RSC
Ms. Ann McNemar, for Dr. Grave, NICHD
Ms. Jennifer Morris, for Mr.Craig Wladyka, Protocol Administration Representative
Dr. Joel Moss, NHLBI
Dr. Maryland Pao, NIMH
Dr. Dilys Parry, NCI SS
Dr. Koneti Rao, NIAID
Dr. Alison Wichman, Acting Exec. Sec.

Absent

Dr. Howard Austin, NIDDK/NIAMS
Dr. Robert Conley, NIDA
Dr. John Gallin, CRC
Dr. Gilman Grave, NICHD
Dr. Marian Johnson-Thompson, NIEHS
Dr. Mitchell Max, NIDCR
Dr. Richard Wyatt, OIR

Guests

Dr. Lura Abbott, OHSR
Ms. Elaine Ayres, CRC
Dr. Frank Balis, NCI
Ms. Valerie Bonham, OGC
Ms. Heather Bridge, NIAID
Ms. Laura Cearnal, CC
Mr. Paul Carlson, NIMH
Dr. Dennis Dixon, NIAID
Ms. Theresa Doged, CRC, OPS
Ms. Bianca Duggins, CC
Ms. Marjorie Gillespie, NINDS
Ms. Anne Gupman, NIDA
Mr. Alex Noury, NINDS
Ms. Charlotte Holden, OHSR
Ms. Donna Howard, NIMH
Ms. Jane Lambert, NIEHS
Dr. Suzanne Pursley-Crotteau, NCI
Mrs. Janet Smith, OHSR (Ret.)
Ms. Patricia Sweet, NHLBI
Ms. Gretchen Wood, NEI
Ms. Marcia Wright, OHSR

1 Minutes of the July 14, 2006 meeting. The minutes were approved.

Dr. Gottesman asked the Chairs and other HSRAC members to introduce themselves since there are now several new or fairly-new IRB Chairs.

Dr. Gottesman thanked Dr. David Goldman for his service as Chair of the NIAAA IRB and for his intellectual contributions to HSRAC discussions. The NIAAA IRB is being merged into the Neuroscience IRB at the end of this month. Dr. Goldman received a round of applause from the HSRAC members.

Dr. Gottesman congratulated Dr. Moss and the NHLBI staff on their recent successful IRB retreat.

2. Update on the Status of Special Government Volunteers. Dr. Gottesman said it is less likely that special government volunteers, such as IRB members, would be defended by the Department of Justice under the federal tort claims act (FTCA). He pointed out that the Department of Justice determined that they would not defend those who volunteered during the Katrina hurricane, although those volunteers are not in the same category as DSMB and IRB members, volunteer surgeons at NIH, etc. Paid IRB members are not covered and a conflict of interest would make volunteers more liable. Special Government Employees (SGEs) would be covered under the FTCA. NIH could seek liability insurance coverage but it is difficult to find an interested insurer. No decisions have been made yet about how to proceed. Ms. Holden pointed out that the Medical Administrative Series chapter on special volunteers currently says that they are covered. She suggested that a legislative remedy is required. Ms. Bonham noted that if there were a suit, it would most likely proceed *via* the investigator, the institution and/or an entire IRB, rather than an individual IRB member.

3. Research Involving Non-English-Speaking Subjects. Dr. Wichman reminded HSRAC members of the March 2003 revision of the Medical Administrative Series issuance M77-2, which included changes to the process for obtaining consent from non-English speaking subjects. This describes procedures for expected and unexpected arrivals at NIH of foreign or non-English speaking research subjects. In cases where the PI expects enrollment of non-English speaking subjects, the IRB requires a translation of the entire consent document and the use of a professional interpreter (not a family member) to assist in the consent process. When non-English speaking subjects unexpectedly arrive to take part in a protocol, there may not be time to translate the entire consent document into the subject's language, and a short form containing the required elements of consent and an oral discussion based on the text of the written English document may be substituted.

This summer an OHSR student surveyed the Institutes to find out the extent of non-English speaking enrollment in NIH protocols. She had interviews with the translation service of the library, the IRB Chairs and Coordinators, the social work department interpreters and several academic institutions. NHLBI, NIAID, NHGRI, NCI and

NINDS enroll the most non-English speaking subjects. Most of the 173 completely translated consent documents are in Spanish. The short form consent has been translated into 24 languages, and all but two are available on the Web. Chairs have the option to expedite the use of the short form provided they are satisfied that safeguards for the subject(s) are adequate. However, Dr. Wichman emphasized that consent is a minor issue in enrolling non-English speaking subjects. It is important that they receive preparatory information in their home countries, and extra support before and when they arrive at NIH. She thought there should be more standardized approaches by the Institutes to do this and to account for religious and cultural differences. She also questioned the adequacy of the short form as a consent tool and suggested the formation of a working group to explore some of the issues. Dr. Gottesman commented on the availability of improved electronic translations.

Dr. Gonzales endorsed the need for support structures for non-English speaking subjects, not only during the consent procedure but before they come to NIH and throughout their participation in a protocol. She cited the case of a Mongolian subject in the ICU for whom no translation service was available when needed during a crisis. Dr. Goldman pointed out that addiction therapy requires oral interaction and for this reason, his IRB in the past has refused to allow enrollment of non-English speakers on some protocols. Dr.Wichman said that non-English speakers can be excluded only for a good scientific reason. Dr. Hazra suggested that a start could be made in designing good information and resource materials for non-English speaking subjects in Spanish, which is the most commonly used foreign language at NIH.

Dr. Wichman believes that because of the comparatively large numbers enrolled, NIH is in a unique position to take the lead in developing good procedures for non-English speaking subjects.

4. Update on the OHSR IRB Evaluation Project. Dr. Wichman said that another OHSR summer student three years ago compiled a draft instrument for use in evaluating IRBs. This instrument was tested this summer in five IRBs; NHLBI, NIAID, NCI, NINDS and NHGRI, by evaluators in groups of three who made two visits to each IRB. The evaluators were Dr. Monica Schaeffer (lay member, NEI IRB), Dr. Gordon Willis, NCI, Dr. Howard Austin, NIDDK, Ms. Melissa Bryant, NHLBI, Dr. Christine Grady, CRC/DCB, Ms. Janet Smith, OHSR (retired), Dr. David Goldman, NIAAA and Dr. Jan Yates, CC, Dr. Lura Abbott, OHSR and Dr. Alison Wichman, OHSR. As a result, there is now a second, amended version of the evaluation instrument. The purpose of the evaluation was not to question IRBs' decisions, but to assess the processes of a convened meeting. Dr. Wichman noted that the AAHRPP does not visit convened IRB meetings during its accreditation process, and it has been questioned in the past whether such evaluations are feasible. Nevertheless, she and the evaluators believe this is a worthwhile and interesting project. Once the instrument is fully developed, it will be shared with HSRAC and she hopes eventually to have outside reviewers come to NIH to test it and to use it for internal review by IRB members.

5. Update on the Neuroscience IRB. Dr. Karp reported that the NIAAA IRB is being merged with NIMH. It will have 14/15 members with a good range of expertise and will meet the last week in September, chaired by Dr. Karp. Subsequently, NEI will be merged with the NINDS IRB and a retreat will be held in December to iron out any problems and plan the final unification of the neuroscience IRBs. [After the meeting, Dr. Goldman and Dr. Gottesman agreed that Dr. Gottesman would write to all the NIAAA IRB members, thanking those who are stepping down and requesting the others to serve on the merged IRB. Formal appointment to the new IRB will be dealt with later.]

Announcements.
(a) This year's PRIM&R meeting will be held in Washington, D.C. on November 15 through 18. Dr. Gottesman encouraged all HSRAC attendees to participate.

(b) Updates to the 1195 form. Dr. Gottesman said the form was reviewed again by the MEC last Tuesday. Most comments have been incorporated, although not everyone may be satisfied.

As a practical solution, it has been decided that NIH will not be responsible for reporting RNO and sender distribution of enrollment on protocols for which it is not the lead institution.

There is now a "not applicable" box to be checked regarding whether NIH's conflict of interest guide has been distributed to outside reviewers. This guide is an internal document and it is not mandatory for outside collaborators to conform to it, although some volunteer to do so. Dr. Balis pointed out that the current version of the guide is still in draft form. The January 2005 approved version of the guide is the one that appears on OHSR's web site. Dr. Gottesman said that he and Dr. Wichman would finalize the current draft, which includes sections regarding IRB members, so that it can be issued with the new 1195 and 1195-1. It has been held up because of the question of who should review Clinical Directors' protocols. The final version will be submitted to the MEC and HSRAC for approval.

Dr. Gottesman said that DEC policy is a separate issue required by regulations and that the ethics review process should not delay any continuing reviews.

(c) Dr. Wichman drew attention to the first of a six-part PBS program on pharmaceutical research, which was due to air at 9:30 p.m. that evening.

(d) Dr. Wichman announced that Dr.Abbott, Ms. Gillespie and Ms. Chaitt would be conducting a site visit to the NIEHS IRB next week.

(e) Dr. Gottesman said there will be another Congressional hearing on conflict of interest involving NIH intramural clinical investigators.

(f) In response to a question, Dr. Gottesman said that he hoped to announce the name of the new Director of OHSR very soon.

The meeting closed at 5:00 p.m. The next meeting will be December 1, 2006.